510(k) Summary

JUL 1 0 2013

Date Prepared: May 2, 2013

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Device Name and Classification

Trade Name:	DLP® Coronary Ostial Perfusion Cannulae Models: 30010, 30011, 30012, 30014, 30050, 30055, 30315, 30317, 30320, 30110, 30112, 30114, 30155, 30212, and 30255.
Common Name:	Cardiopulmonary bypass vascular catheter, cannula, or tubing
Regulation Number:	21 CFR 870.4210
Product Code:	DWF
Product Classification:	Class II

Predicate Devices

K034058	Spherical Tip Coronary Ostial Cannulae

Device Description

These coronary Cannulae consist of basket-style tip, soft (silicone) tip, or spherical tip which is attached to a malleable stainless steel tube, or a soft bulb beveled tip with an integral silicone body. The Cannulae terminate with a locking female luer fitting. The French diameter is

measured at the base of the tip adjacent to the sealing flange or across the diameter for the soft bulb beveled tip style. The Cannulae are nonpyrogenic, single use, and sterile.

Indications for Use
These Cannulae are intended for use in conjunction with cardiopulmonary bypass surgery up to six hours or less for delivery of cardioplegia solutions directly to the coronary arteries.

Comparison to Predicate Devices
A comparison of the modified product to the currently marketed predicate products (K034058) indicates the following similarities:

- Same intended use
- Same technological characteristics
- Same operating principle
- Same design features
- Same base materials (Polyvinyl Chloride (PVC), Polypropylene, and Stainless steel)
- Same shelf life

Summary of Performance Data

Verification and validation testing has demonstrated that the DLP Coronary Ostial Perfusion Cannula are substantially equivalent to the predicates.

The following performance tests were conducted:

Modifications	Verification/Validation	Results
Silicone to new Silicone due to supplier obsolescence.	Burst strength relative to predicate material.	Pass
Organic to synthetic barium sulfate.	Tip component tested for tensile pull-off force.	Pass
	Biocompatibility Assessment.	Pass – no impact to biocompatibility
Polypropylene to new Polypropylene due to supplier obsolescence.	Hub tested for Tensile Pull-Off Force and Torsional Twist-Off Force.	Pass
	Biocompatibility Assessment.	Pass – no impact to biocompatibility

Conclusion
Medtronic has demonstrated that the modifications made to the DLP® Coronary Ostial Perfusion Cannulae product family described in this submission result in a substantially equivalent device because the fundamental scientific principle, operating principle, design features and intended use are unchanged from the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-002

July 10, 2013

Medtronic CardioVascular, Inc.
c/o Kevin Lam
8200 Coral Street NE
Mailstop MVS83
Mounds View, MN 55112

Re: K131269
Trade/Device Name: DLP Coronary Ostial Perfusion Cannula
Regulation Number: 21 CFR 870.4210
Regulation Name: Cardiopulmonary Bypass Vascular Catheter, Cannula, or Tubing
Regulatory Class: Class II
Product Code: DWF
Dated: June 13, 2013
Received: June 14, 2013

Dear Mr. Lam:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Bram D. Zuckerman, Ph.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Statement of Indications for Use

510(k) Number: K131269

Device Name: DLP® Coronary Ostial Perfusion Cannulae

Indications for Use:

These Cannulae are intended for use in conjunction with cardiopulmonary bypass surgery up to six hours or less for delivery of cardioplegia solutions directly to the coronary arteries.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

M A Hillebrenner